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REMARKS/ARGUMENTS

Claims 20-34 remain in this application. Claims 1-19 and 29 have been canceled.

All of the pending claims have been amended to clarify what applicants regard as their invention. The phrase "solid oral" has been added to the claims to avoid any antecedent basis issues and to clarify that the claimed dosage form is a solid oral dosage form. Support for these amendments may be found beginning on page 22, line 1 et seq. Additionally, "pregelatinized starch" has been added to claims 1, 33 and 34. This element was added from claim 29, which has been previously searched and examined. Support for these amendments may be found for example on page 4, line 20 et seq. and page 5, line 5. No new matter is introduced by these amendments. Accordingly, applicants respectfully request entry of these amendments as they place the application in condition for allowance.

The rejection of claims 20, 21, 25, 26 and 32-34 under 35 U.S.C. 102 (b) as being anticipated by Rickey et al. (USPN 5,792,477) has been reviewed. However in view of the amendments to the claims reconsideration and withdrawal of this rejection is requested.

Rejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Arkley, 59 CCPA 804, 807, 455 F2d 586, 587, 172 USPQ 524, 526 (1972). In other words to constitute an anticipation, all the material elements recited in the claim must be found in one unit of prior art. Soundscriber Corp. v. United States, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct.Cl. 1966). In view of the amendment to claim 20, applicants respectfully submit that not all the material elements recited in the claim are not found in Rickey et al. Applicants' attorney note that Rickey et al is directed to the formation of microspheres, which does not utilize pregelatinized starch to maintain the controlled release in a release media with changing ionic strength. Accordingly, applicants attorney respectfully submit that Rickey et al. does not anticipate claims 20, 21, 25, 26 and 32-34.

The rejection of claims 22-24 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosure of Rickey et al (USPN 5,792,477) and Shimizu et al (USPN 5,824,339) has

been reviewed. Applicants' attorney respectfully requests reconsideration and withdrawal of this rejection in view of the following comments.

As previously mentioned Rickey et al. is directed to the formation of microparticles. Rickey et al. does not disclose the use of pregelatinized starch to maintain the controlled release in a release media with changing ionic strength. Therefore applicants' attorney respectfully submits that the present invention is patentably distinguishable from Rickey et al.

Shimizu et al. is directed to an effervescent composition comprising a core-shell powder consisting of a fine granular core spray coated with a liquid mixture containing a water-soluble polymer and at least one physiologically active substance and enteric coating film an effervescing component and an auxiliary effervescing agent which provides for controlled release of the physiologically active substance and is useful for preparing a uniform solution or suspension having a refreshing sensation on ingestion. See abstract.

The combination of Rickey et al. and Shimizu et al. does not render the present invention obvious. Rickey et al. discloses an injectable microparticles (column 17, lines 30 et seq.). Applicants' attorney in fact does not believe that the references cited establish that the microparticles described in Rickey et al. would be suitable to provide a controlled release oral dosage form. Applicants' attorney additionally fails to understand how the teaching of Rickey et al. can be combined with Shimizu, which relates to an oral effervescent dosage form. There is nothing in Rickey et al or Shimizu to motivate the combination of these two patents with such different delivery means. Accordingly, applicants' attorney submits that because the patents are not properly combinable that a *prima facie* case of obviousness has not been established and that this rejection should be withdrawn.

Additionally, applicants' attorney wishes to point out that 9-hydroxyrisperidone is an antipsychotic not an antibiotic. Thus, the office action has not linked the relevance of the delivery of the drugs described in Shimizu et al. to the delivery of the antipsychotic compounds described in Rickey et al. Applicants' attorney notes that Shimizu et al. does not specifically mention the antipsychotic compounds described in Rickey et al.

Further, the combination of these two patents, if proper, does not suggest or disclose the claimed invention, which is a hydrophilic controlled release solid formulation containing pregelatinized starch to maintain the controlled release in a release media with changing ionic strength. It is not apparent to the applicants' attorney how the combination of the injectable microparticle formulation of Rickey et al. and an effervescent composition of Shimizu would provide any motivation to a make a hydrophilic controlled release solid oral formulation. Accordingly, applicants' attorney respectfully requests reconsideration and withdrawal of the rejection of claims 22 - 24 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosure of Rickey et al. and Shimizu et al.

The rejection of claims 26-31 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Rickey et al and Yajima et al. (USPN 5,972,373) has been considered. However, in view of the following comments applicants attorney respectfully requests reconsideration and withdrawal of this rejection.

As previously mentioned Rickey et al. is directed to the formation of microparticles. Rickey et al. does not disclose the use of pregelatinized starch to maintain the controlled release in a release media with changing ionic strength. Therefore applicants' attorney respectfully submits that the present invention is patentably distinguishable from Rickey et al.

Yajima et al is directed to a composition for oral administration comprising an unpleasant tasting drug a high polymer soluble in the stomach and a monglyceride in the β-crystal form. See abstract. Yajima et al. does not disclose the formulation of antibiotic agents in abstract contrary to the statement in the prior office action. Applicants' attorney notes that Yajima does mention the in column 2, line38 et seq. that psychotropic drugs (e.g. chlorpromazine) which is an antipsychotic, may be used in Yajima's formulation. However Yajima et al. does not mention or list the antipsychotic compounds described in Rickey et al.

Yajima et al is also directed to the formation of taste masking composition in which a monoglyceride is present in the β-crystal form. Yajima does not disclose or describe a

hydrophilic controlled release solid formulation comprising 9-hydroxyrisperidone, a pharmaceutically acceptable acid addition salt thereof, an N-oxide form thereof, or a stereochemically isomeric form thereof, and one or more viscous hydrophilic polymers.

The combination of Rickey et al with Yajima et al is inappropriate and does not establish a *prima facie* case of obviousness. As previously mentioned Rickey et al. discloses a microparticle that is described as being delivered by injection (column 17, lines 45 et seq.). There is no suggestion that the injectable compounds of Rickey et al. require taste masking. Applicants' attorney in fact does not believe that the references cited establish that the microparticles described in Rickey et al. would be suitable to provide a controlled release oral dosage form. Similarly Yajima does not disclose or suggest that his formulation would provide a controlled release formulation not the use of the compound of Rickey et al to make a hydrophilic controlled release solid formulation containing 9-hydroxyrisperidone. Accordingly, applicants' attorney respectfully requests reconsideration and withdrawal of this rejection.

Regarding the recitation of specific ratios and concentrations and amounts of drug, since the level of skill of one of ordinary skill in this art has not been established, nor have the recited ratios and concentrations or amount of drug been shown in the art to represent routine optimization applicants' attorney submits that until such information provided in some manner that the rejection of the claims on the basis of these general statements is inappropriate. Until the examiner provides art or a declaration on these points these rejection are not supported by the record and are improper. Consequently applicant requests reconsideration and withdrawal of these rejections.

Although the prior rejections have been withdrawn applicants' attorney maintains that those rejections in the previous Office Action were in error for the reasons of record.

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Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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